

REMARKS

Claims 1-19 are pending. Claims 1, 4-14, and 16-19 have been amended. Claims 2-3 have been cancelled. Claim 20 is added.

The USPTO objected to the abstract of the disclosure. Applicants corrected the abstract, as suggested by the examiner.

Claims 1, 4-5, 7, 14-16, and 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Publication Entitled ASTM Standard Specification for Wrought 35Cobalt-35Nickel-Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R 30035), hereafter "ASTM". Claim 1 is directed to a medical electrical lead comprising an elongated conductor including one or more wires made of a modified MP35N alloy, wherein the alloy is formed from a melt composition modified to reduce an amount of titanium-based inclusion forming elements. The modification of the melt composition includes "eliminating the titanium as an additive to the melt composition, and wherein the alloy comprises less than approximately .001% titanium by weight." Claim 4 is directed to a medical electrical lead comprising an elongated conductor including one or more wires made of a modified MP35N alloy wherein "the alloy is formed from a melt composition modified to reduce an amount of titanium-based inclusion forming elements; and wherein the inclusion forming elements include a gaseous oxygen and nitrogen and the modification of the melt composition includes eliminating the gaseous oxygen and nitrogen under high vacuum conditions."

ASTM relates to an improved process which overcomes the limitations relating to large cubical TiN particles in standard ASTM F 562 wire for pacing leads. The USPTO asserts that ASTM teaches eliminating the titanium as an additive to the melt composition, as stated in claim 1. Reference is made specifically to Table 2 which shows a reduction in Titanium from 1% maximum in standard ASTM F 562 to 0.01% in the modified 35N LT Alloy. ASTM does not specify the improved process for reducing the Titanium from 1% maximum to 0.01%. As the Examiner is well aware, in order for a reference to anticipate a

claim, that reference must teach each element of the properly construed claim. Contrary to the Examiner's assertion, ASTM fails to teach, among other things, eliminating Titanium as an additive to the melt composition and the alloy comprising less than approximately 0.001% Titanium by weight.

With regard to claim 4, the USPTO asserts that ASTM teaches eliminating gaseous oxygen and nitrogen under high vacuum conditions. The modified 35N LT alloy disclosed by ASTM includes inclusions with high concentrations of magnesium and oxide (page 2 of 7, under Table 1). As such, oxygen is available to form an oxide in the inclusion. Accordingly, ASTM does not teach or suggest a modified melt composition wherein the modification includes eliminating gaseous oxygen and nitrogen under high vacuum conditions.

With regard to claim 14, the Examiner states that ASTM inherently discloses that the titanium based inclusions have an average number of less than 100,000 per square inch since the titanium content is less than 0.01. The Applicants traverse. The number of inclusions per square inch will be dependent on factors other than the total titanium content, *e.g.*, the size of the inclusions through which the total titanium content is distributed. Applicants note that ASTM reports the titanium content to be 0.01%, not less than 0.01% as stated by the Examiner. ASTM reports a mean number of inclusions of 638 per 1.77 mm² sample (see Testing on page 1 of 7 and Table 1) which is greater than 100,000 per square inch (414,193 per square inch). As such, Applicants assert that ASTM does not teach or suggest an average number of less than 100,000 titanium-based inclusions per square inch.

With regard to claim 15, the Examiner states that ASTM inherently discloses that the average number of titanium-based inclusions has a maximum diameter not exceeding approximately 1 micron. The Applicants traverse. ASTM reports the mean size of the largest inclusions found in the modified 35N LT alloy was 4.2 µm (Table 1). As such, ASTM fails to teach or disclose the average number of titanium-based inclusions having a maximum diameter not exceeding

approximately 1 micron. For at least these reasons, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Claims 9-10 and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over ASTM. As discussed above, ASTM reports an alloy having 0.01% Titanium. ASTM does not teach or suggest an alloy having less than 0.001% Titanium as stated in claim 9. Applicants submit that, since production of an alloy modified to reduce Titanium-based inclusions will depend on specialized processing, producing the modified alloy is not merely a matter of discovering the optimum or workable ranges. ASTM has not specified the alloy processing modifications made to reduce the Titanium content and has therefore not taught the general conditions of the present claims.

The remainder of the claims are patentably distinct from the reference for the same or similar reasoning. The Examiner's reference to "Applicants Own Admission of Prior Art" relates to configurations of lead conductors and does not remedy the deficiencies of the ASTM reference relating to an alloy having less than 0.001% Titanium (as stated in claims 1 and 9) and an alloy having an average number of less than 100,000 titanium-based inclusions per square inch (as stated in claim 14). Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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Date

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